

DETAILED ACTION

1. This is the initial Office action based on the 10/561,915 application filed on April 10, 2006 which is a 371 of PCT/IB2004/02395 filed on June 24, 2004, which claims priority to US Provisional Application No. 60/490,516.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitation "second positioning means" and claim 17 recites "first positioning means". There is insufficient antecedent basis for this limitation in the claim. The examiner assumes the applicant meant to recite, first and second positioning elements respectively.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. **Claims 1, 3, 5, 11, 15, 16, 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 in view of Krafft US 2,679,778.

Lin discloses vertebral osteosynthesis equipment, comprising:

one or more bony anchoring members, at least one of said bony anchoring members comprising a proximal threaded stud and a base portion, the proximal threaded stud having a first end connected to the base portion and a free second end opposed to said first end, said base portion configured to anchor to a vertebra (see fig below);

a linking rod (as seen in Fig below);

a connecting part configured to engage with said proximal threaded stud of said at least one of said anchoring members, and further configured to connect to said

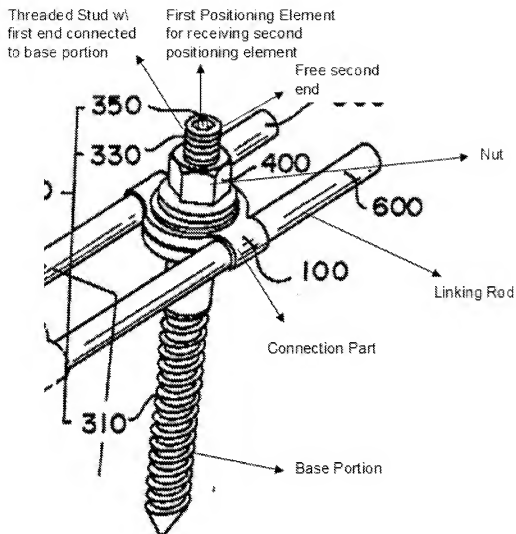
linking rod thereby to connect said linking rod to said at least one of said anchoring members (as seen in Fig below);

a nut configured to engage in threaded engagement with said proximal threaded stud to secure said connecting part (see Fig below); and

at least one extension piece having a heard portion (see Col 4 line 65, where an extension piece is used on the first positioning element),

wherein said free second end of said proximal threaded stud has a first positioning element and said end distal portion of said extension piece has a second positioning element, said first and second positioning elements configured in a first mode to removably engage concentrically with each other to mount said end distal portion of said extension piece on said free second end of said proximal threaded stud, and said first and second positioning elements further configured in a non-engagement second mode to disengage from each other such that the extension piece is not mounted on said proximal threaded stud (see Col 4 lines 65), and

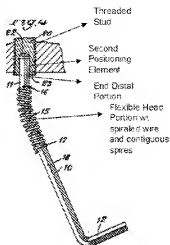
wherein said nut is configured to cooperate with the proximal threaded stud to secure said connecting part at said first end, the first and second positioning elements are configured to axially connect the proximal threaded stud with the extension piece, the extension piece can be removable from the proximal threaded stud upon implantation, the first positioning element comprises a bore (as seen in Fig below and see Col 4 lines 10-30, 63-68, Col 5 lines 1-5, where the nut cooperates with the threaded stud).



Lin does not disclose the extension piece having a head portion and an end distal portion opposed to said head portion, said end distal portion configured to connect to said free second end of said proximal threaded stud and to slidably receive said connecting part from the head portion to the end distal portion such that said connecting part may engage upon said proximal threaded stud, wherein each of said head portion and said end distal portion have an outermost external diameter configured such that the nut, in coaxial engagement with said extension piece, slides freely over an entire

length of said extension piece, wherein the head portion of the extension piece is a flexible structure configured to be positioned askew to a direction of extension of the extension piece, wherein the flexible structure is a wire in a spiral form with a plurality of contiguous spires, the outermost diameter of the end distal portion is smaller than an outermost diameter of the proximal threaded stud.

However, Krafft discloses the use of extension piece having a head portion and an end distal portion opposed to said head portion, said end distal portion configured to connect to a free second end of said proximal threaded stud, wherein the extension piece has an outer diameter smaller than the diameter of the threaded stud such that a each of said head portion and said end distal portion have an outermost external diameter configured such that the nut, in coaxial engagement with said extension piece, slides freely over an entire length of said extension piece, wherein the head portion of the extension piece is a flexible structure configured to be positioned askew to a direction of extension of the extension piece, wherein the flexible structure is a wire in a spiral form with a plurality of contiguous spires, the outermost diameter of the end distal portion is smaller than an outermost diameter of the proximal threaded stud, the second positioning element comprises a rod and the first positioning element (see fig below and Col 2 lines 15-30), wherein the flexible nature of the extension piece allows it to be used in tight work places where otherwise non flexible tools would be difficult of impossible to handle (see Col 1 lines 5-8).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the extension piece of Lin to include the flexible head portion in view of Kraff because the flexible nature of the extension piece allows it to be used in tight work places where otherwise non flexible tools would be difficult or impossible to handle, wherein a nut would be capable of sliding freely over the entire length of the extension piece.

8. **Claims 6-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 and Krafft US 2,679,778 as applied to claim 5 above, and further in view of Tool US 2,404,580.

The combination of Lin and Krafft disclose the claimed invention as discussed above but does disclose the flexible structure is made out of a metal.

Tool discloses a flexible element made out of a metal (#17 see Col 2 lines 10-20), wherein the metal material allows the flexible structure to flex (see Col 2 lines 10-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Lin and Krafft to have the flexible element be made out of a metal because it is a simple substitution of known material for another to obtain predictable results of producing a flexible element.

9. **Claims 2, 9, 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 in view of Krafft US 2,679,778.

The combination of Lin and Krafft disclose the claimed invention as discussed above where the first positioning element comprises a bore and the second positioning element comprises an integral rod (as seen in Fig above in claim 1, but the examiner notes that Lin teaches a first positioning element in the form of an integral rod #340), wherein the first and second poisoning elements are configured to connect axially and the head portion is a flexible structure but does not disclose the first positioning element is an integral rod and the second positioning element is the bore.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made have the first positioning element is an integral rod and the second positioning element is the bore, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

10. **Claims 2, 4, 9, 10, 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 in view of Krafft US 2,679,778, as applied to claim 1, 3, above and in further view of .

The combination of Lin and Krafft disclose the claimed invention as discussed above where the head has a flexible structure, the first positioning element comprises a bore and the second positioning element comprises an integral rod (as seen in Fig above in claim 1), wherein the first and second poisoning elements are configured to connect axially and the head portion is a flexible structure but does not disclose the first positioning element is an integral threaded rod and the second positioning element is tapered/threaded bore, wherein the rod.

Stillman discloses an extension piece (#76) with a second positioning element is a threaded/tapered bore to mate with an first positioning element of a threaded stud in the form an integral threaded rod (#82) where this configuration helps to seat/fasten the threaded stud (Col 8 lines 5-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Lin and Krafft to reverse parts, wherein the first positioning element is an integral threaded rod and the second positioning element is tapered/threaded bore, in view of Stillman because it is a simple substitution of known type of connecting means between an extension piece and threaded stud to provide predictable results of helping to fasten a stud.

11. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 in view of Krafft US 2,679,778.

Lin discloses a vertebral osteosynthesis equipment, comprising:

a first bony anchoring member comprised of a proximal threaded stud and a base portion, the proximal threaded stud having a first end connected to the base

portion and a free second end opposed to said first end, said base portion configured to anchor to a vertebra (as seen in Fig below);

a connecting part configured to engage with said proximal threaded stud of said first bony anchoring member (as seen in Fig below);

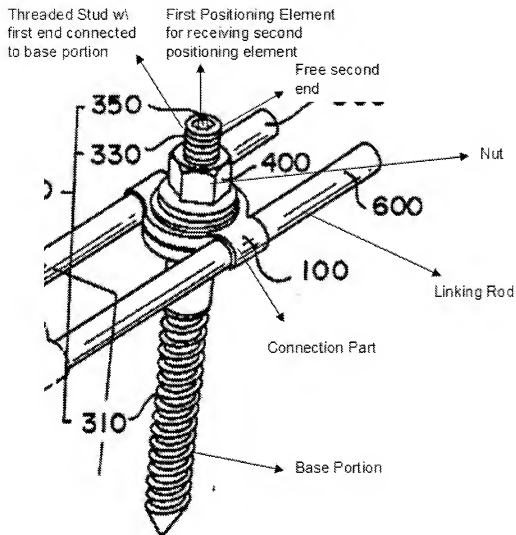
a linking rod configured to connect to said connecting part of said first bony anchoring member, and further configured to connect to a second bony anchoring member (as seen in Fig below);

a nut configured to engage on said proximal threaded stud to secure said connecting part (as seen in Fig below and Col 4 lines 12-34, 62-68, Col 5 lines 1-5); and

an extension piece having a head portion and an end distal portion opposed to said head portion, said end distal portion configured to connect to said free second end of said proximal threaded stud and to slidably receive said connecting part from the head portion to the end distal portion such that said connecting part may engage upon said proximal threaded stud (see Fig below and see Col 4 line 65);

wherein said free second end of said proximal threaded stud has a first positioning element and said end distal portion of said extension piece has a second positioning element, said first and second positioning elements configured to engage concentrically with each other and to position said end distal portion of said extension piece on said free second end of said proximal threaded stud (see Fig below and see Col 4 line 65, where the extension piece connects the free second end) and

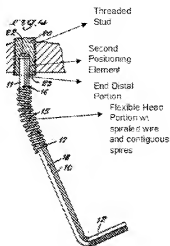
wherein said nut is configured to cooperate with the proximal threaded stud to secure said connecting part at said first end (as seen in Fig below and see Col 4 lines 10-30, 63-68, Col 5 lines 1-5, where the nut cooperates with the threaded stud).



However Lin does not disclose each of said head portion and said end distal portion have an outermost external diameter configured such that the nut, in coaxial engagement with said extension piece, slides freely over an entire length of said extension piece, wherein the head portion is a flexible structure configured to be

positioned askew to a direction of extension of the extension piece, wherein the flexible structure is a wire wound to have a spiral form, a plurality of contiguous spires.

However, Krafft discloses the use of extension piece having a head portion and an end distal portion opposed to said head portion, said end distal portion configured to connect to a free second end of said proximal threaded stud, wherein the extension piece has an outer diameter smaller than the diameter of the threaded stud such that a each of said head portion and said end distal portion have an outermost external diameter configured such that the nut, in coaxial engagement with said extension piece, slides freely over an entire length of said extension piece, wherein the head portion of the extension piece is a flexible structure configured to be positioned askew to a direction of extension of the extension piece, wherein the flexible structure is a wire in a spiral form with a plurality of contiguous spires, the outermost diameter of the end distal portion is smaller than an outermost diameter of the proximal threaded stud (see fig below and Col 2 lines 15-30), wherein the flexible nature of the extension piece allows it to be used in tight work places where otherwise non flexible tools would be difficult of impossible to handle (see Col 1 lines 5-8).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the extension piece of Lin to include the flexible head portion in view of Kraff because the flexible nature of the extension piece allows it to be used in tight work places where otherwise non flexible tools would be difficult or impossible to handle, wherein a nut would be capable of sliding freely over the entire length of the extension piece.

12. **Claims 20-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 and Krafft US 2,679,778 as applied to claim 19 above, and further in view of Tool US 2,404,580.

The combination of Lin and Krafft disclose the claimed invention as discussed above but does disclose the flexible structure is made out of a metal.

Tool discloses a flexible element made out of a metal (#17 see Col 2 lines 10-20), wherein the metal material allows the flexible structure to flex (see Col 2 lines 10-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Lin and Krafft to have the flexible element be made out of a metal because it is a simple substitution of known material for another to obtain predictable results of producing a flexible element.

13. **Claims 1-4, 8, 16, 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US 5,613,968 in view of Craig US 5,507,817.

Lin discloses a bony anchoring member comprising a proximal stud and a base portion (as seen in Fig below), a linking rod, a connecting part engaged to the proximal stud and to connect to the linking rod (as seen in Fig below), a nut in threaded engagement with the proximal stud (as seen in Fig below and see Col 4 lines 12-34, 63-68).

However Lin does not disclose an extension piece with a head portion and a distal end portion to contact a second free end of the proximal threaded stud, wherein the free second end of the proximal stud has a first poisoning element in the form of an integral threaded rod to engage a threaded bore in the distal end of the extension piece.

However Craig discloses using an extension piece (#20) which has a distal end (area containing the bore #34) and a head portion (proximal end of the extension piece, opposite the distal end), a stud (#10), wherein the free end of the stud has a threaded integral rod (#32) which mates with the threaded/tapered bore (#34) of distal end of the extension piece (see Fig below and Col 4 lines 35-48), wherein the threaded connection is made to adjust the length of the stud in order to provide a stud with different lengths (see abstract, Col 6 lines 35-42 as well as Fig 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the equipment of Lin to have a second free end with an integral threaded rod and the extension piece with a tapered hole/bore, where the rod and bore are threadingly connected to each other, in view of Craig so that the length of the stud can be adjusted adjust in order to provide a stud with different lengths, wherein the extension piece would obviously also have threads to match the threaded stud to because the extension piece is merely used to extend the length of the threaded stud, wherein the nut can slide freely over the entire length of the extension piece, wherein the extension piece and the threaded stud can shift between a first move and second mode, where the extension piece can be mounted onto and removed from the proximal threaded stud.

Response to Arguments

14. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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